# CHAPTER IV

# COVERED SERVICES AND LIMITATIONS

**CHAPTER IV**
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## COVERED SERVICES

General Information

The policies described in this chapter apply to all enrolled providers of pharmaceutical services.

Drugs, both legend and non-legend, covered by Virginia Medicaid will be provided only on the prescription of a practitioner qualified to prescribe and will be dispensed through a licensed pharmacy or a dispensing physician, in accordance with Virginia State Board of Pharmacy procedures and licensure.

Effective for claims submitted on and after July 1, 2002, the Virginia Medicaid Program will pay for a maximum of a 34-day supply of medication per prescription per patient in accordance with the prescriber's orders and subject to Board of Pharmacy regulations. For prescription orders whose quantity exceeds a 34-day supply, refills may be dispensed in sufficient quantity to fulfill the prescription order within the limits of federal and state laws and regulations.

Coverage and Limitations

Prescription services are provided to Medicaid recipients as described below.

Legend drugs are covered with the following exclusions:

- OBRA 90 non-rebated drug products - Drugs distributed or manufactured by certain drug manufacturers or labelers that have not agreed to participate in the Federal Drug Rebate Program (Effective date April 1, 1991).
- Agents used for anorexia or weight gain.
- Agents used to promote fertility.
- DESI (Drug Efficacy Study Implementation) drugs considered by the Food and Drug Administration (FDA) to be less than effective. Compound prescriptions which include a DESI drug are not covered.
- Drugs which have been recalled.
- Drugs used for hair growth.

- Vaccines for routine immunizations, except for vaccines furnished free of charge by the vaccine program and except for pharmacist-administered vaccines under the protocol specified in "Reimbursement of Vaccines" in this chapter.
- Experimental drugs or non-FDA-approved drugs.
- Drugs used only for cosmetic purposes
- Drug products dispensed after the labeled expiration date of the product

**Specific Requirements for Individual Legend Drugs**

- Clozaril or clozapine - is authorized when the following conditions are applicable: [Effective July 25, 1991]
  - Medicaid-eligible recipients must have a Clozaril National Registry number.
  - Each registered case with a number is required to comply with the Food and Drug Administration (FDA) approved indications for blood and prescription monitoring.
  - A monitoring fee will be allowed on a weekly basis based on the current dispensing fee rate and the use of 9999999275 for 100mg and 9999999276 for 25mg for the submission of claims.
- Total Parenteral Nutrition (TPN) - is authorized only when used as the sole source of nutrition and the following conditions are applicable:
  - There is a physician's statement of medical necessity in the patient record indicating the diagnosis with a brief clinical history;
  - The short- and long-term plans for the requested service are given; and
  - The name and address of the pharmacy supplying the prescription are given.
- Growth Hormone - is authorized when the following conditions are applicable:
  - There is a physician's statement of medical necessity in the patient record indicating the diagnosis with a brief clinical history;
  - The short- and long-term plans for the requested service are given; and
  - The name and address of the pharmacy supplying the prescription are given.
- Norplant - is reimbursable only when dispensed for physician administration.

- Viagra (Sildenafil) tablets when prescribed for erectile dysfunction are covered for males over the age of 21. The allowable quantity is 4 tablets per consecutive 30-day period.

- Anti-Hemophilia Factor – Effective July 1, 2002, pricing of this product shall be according to guidelines for best pricing established by DMAS after review of market factors and appropriate volume purchasing discounting. Prices will be determined by proposals from specialty pharmacy providers and include coordination of care for the recipient. Payment criteria shall take into account a percentage reduction in product reimbursement and include specified services. Anti-Hemophilia Factor will be reimbursed only to providers participating in this contractual program.

**Specific Requirements for Rebated Drugs**

Virginia collects a drug rebate on Medicaid prescriptions dispensed. Fifty percent of the funds collected are returned to HCFA. The remaining funds go to the Commonwealth of Virginia and are not returned to the Medicaid drug budget. Virginia Medicaid, the Health Care Financing Administration (HCFA), and the drug manufacturers may all request audits of provider records. The following policies must be followed:

- The NDC code entered on the pharmacy invoice must be the NDC code for the actual drug dispensed.

- The NDC code entered on the pharmacy invoice must be the correct NDC code for the drug at the time of dispensing. (Obsolete NDC codes do not capture rebates.)

- Product use data must be well documented. (Drug manufacturers will not pay Virginia drug rebates on products if use data are not well documented. Manufacturers can request program audits to determine what specific products have been dispensed.)

Coverage of Non-legend drugs (Over-The-Counter drugs) is described below:

- Coverage is allowed for family planning drugs and supplies and insulin for all recipients, and syringes and needles for all recipients except those residing in nursing facilities.

- Diabetic test strips are covered for recipients under 21 years of age only (Effective July 1989)

- Coverage of Specific Therapeutic Categories:

  A) Covered for recipients residing in nursing facilities, are:

  - Analgesics

- Antacids
- Antidiarrheal preparations
- Antivertigo and antinauseant preparations
- Cough and cold preparations
- Dermatologicals
- Hemorrhoid preparations
- Laxatives
- Ophthalmic and otic preparations
- Vitamins, minerals, and hematinics

B) Covered for outpatients, when used as less costly alternatives to prescription drugs, are:

- Analgesics, oral
- Antacids
- Antidiarrheals
- Antifungals, topical
- Antihistamines
- Anti-infective agents, vaginal
- Anti-inflammatory agents, oral
- Antiulcer Preparations
- Hematinics
- Hydrocortisone, topical
- Laxatives, bulk producers and stool softeners
- Pediculocides/scabicides
- Vitamins, pediatric (in established deficiencies)
- Vitamins, prenatal
- Vitamins or minerals for dialysis patients

- The Medicaid Pharmacy Program does not cover the following non-legend items:

  - Dietary items, such as sugar or salt substitutes;

  - Enteral nutrition;

  - Supplies, including (but not limited to) antiseptics (e.g., hydrogen peroxide, Merthiolate, tincture of iodine, Mercurochrome, rubbing alcohol, antiseptic soaps, boric acid), first aid preparations (e.g., Band-Aids, gauze, adhesive tape), and miscellaneous supplies, such as cervical collar, asepto syringe, IV sets, and support stockings;

  - Drug products dispensed after the labeled expiration date of the product;

  - Hair growth products;

- Personal items, including (but not limited to) dentifrices, dental adhesives, toiletries, and other items generally classified as cosmetic; mouthwash and gargles; shampoos (non-legend) and soaps; cough drops; depilatories, suntan lotion, and hair bleaches;

- Products used for cosmetic purposes;

- Over-the-counter medications, except as listed on the covered drug list; and

- Alcoholic beverages.

Non-legend Control Schedule V drugs are covered as legend regardless of the quantity dispensed.

## HOME INTRAVENOUS THERAPY

The following policy is effective for pharmacy claims with dates of service on and after July 1, 1998.

Home Infusion Therapy: Service Day Rate

Home Infusion Therapy is the intravenous administration of fluids, drugs, chemical agents, or nutritional substances to recipients in the home setting. DMAS will reimburse for the services, supplies, and drugs only when they are determined to be:

- Medically necessary to treat a recipient's medical condition;

- In accordance with accepted medical practice; and

- Not for the convenience of the recipient or the recipient's caregiver.

For a provider to use the Home Infusion Therapy service day rate method of billing, the recipient must:

- Reside in either a private home or a domiciliary care facility, such as an adult care residence. Recipients in hospitals, nursing facilities, rehabilitation centers, and other institutional settings are not eligible for this service;

- Be under the care of a physician who prescribes the home infusion therapy and monitors the progress of the therapy;

- Have body sites available for I.V. catheter or needle placement or have central venous access; and

Be capable of self-administering or have a caregiver who can be adequately trained, is capable, and is willing to administer/monitor home infusion therapy safely and efficiently follow the appropriate teaching and adequate monitoring. In those cases where the recipient is incapable of administering or monitoring the prescribed therapy, and there is no adequate or trained caregiver, it may be appropriate for a home health agency to administer the therapy.

Provider Eligibility

Providers must have a valid Virginia Medicaid provider number to participate in the home I.V. therapy program. Providers eligible to participate in this program are:

- I.V. therapy providers;
- Home health agencies;
- Pharmacies; and
- DME providers.

A participating provider must be a Virginia Medicaid provider, to include the following:

- Meet any state licensing and certification requirements;
- Render infusion therapy covered services;
- Use Medicaid-established billing guidelines; and
- Accept Medicaid reimbursement as payment in full.

Therapy Coverage

Medicaid has assigned a service day rate code and reimbursement rate for each of the covered therapies:

- Hydration therapy;
- Chemotherapy;
- Pain management;
- Drug therapy; and
- Total parenteral nutrition (TPN).

Service Day Rate Definition

This payment methodology provides a fixed amount for each day of infusion therapy. The service day rate (per diem) reimburses for all services delivered in a single day. This payment methodology will be mandatory for the reimbursement of all Home I.V. Therapy services, unless the recipient is enrolled in one of the waivered services outlined under "Special Considerations." Service day rates are based on an average day of service, and there will be no additional reimbursement for special or extraordinary services.

The service day rate payment will be in two service categories: durable medical equipment (DME) and pharmacy. In the event of incompatible drug administration, the separate HCPCS code Z7778 has been developed to allow for the rental of a second infusion pump and the purchase of an extra administration tubing. When applicable, this code may be billed in addition to the other service day rate codes. There must be documentation to support the use of this code on the I.V. Implementation Form (DMAS-354). Proper documentation includes the need for pump administration of the medications ordered, the frequency of administration to support that they are ordered simultaneously, and an indication of incompatibility.

Items in the DME service day rate include all supplies required to administer I.V. therapy, including but not limited to, the:

- I.V. pump/pole rental/control devices;
- Tubings, adapters, caps, needles, filters, cannulas, extension sets, and alcohol swabs; and
- I.V. start kits and central venous catheter dressing kits.

Items in the Pharmacy service day rate include the:

- Diluent for the therapeutic agent;
- Mixing and compounding;
- Flush kits and solutions (heparin and saline); and
- Cassettes and bags/mini-bags.

Service day rates, by type of therapy, for basic components as delineated above* are:

| | |
|---|---|
| Z7779 Pharmacy - Hydration Therapy | $ 8.00 |
| Z7780 Pharmacy - Chemotherapy | 25.00 |
| Z7781 Pharmacy - Pain Management Therapy | 12.00 |
| Z7782 Pharmacy - Drug Therapy | 27.00 |
| Z7783 Pharmacy - TPN Therapy | 150.00 |

*Payment for the active ingredient is billed separately using the Daily Pharmacy Drug Claim Ledger form (DMAS-173), Point-of-Service (POS) on-line billing, or other approved electronic billing method.

Drugs used in addition to I.V. therapy, such as intramuscular and subcutaneous injections (Compazine, insulin, etc.) and subcutaneous therapies for hydration and/or pain management, are not covered under the home I.V. service day rate policy. These medications and their associated DME supplies must be ordered and billed separately according to current Medicaid guidelines.

Drugs

Drugs providing the therapy's active ingredient are reimbursed according to Medicaid's payment methodology. Payments for the active ingredient shall be the lowest of:

- The upper limit established by the Health Care Financing Administration (HCFA) for multiple source drugs, except if "Brand Necessary" is noted on the prescription by the prescriber;

- The Virginia Maximum Allowable Cost (VMAC) established by DMAS for multiple source drugs listed on the VVF;

- The estimated acquisition cost (EAC) established by DMAS (effective for services on and after July 1, 2002, EAC is the Average Wholesale Price minus 10.25% [AWP – 10.25 %]); or

- The provider's usual and customary charge to the public, as identified by the claim.

Dispensing fees shall be added to the product cost when applicable. One dispensing fee per month per patient per NDC will be allowed, and the patient copay shall be deducted if applicable.

Multiple Therapies

Multiple therapies of the same therapy are included in one service day rate of reimbursement. For example, if a recipient receives two antibiotics under drug therapy on the same day, the provider may only bill one service day rate for the pharmacy services. The individual antibiotics may be billed separately as active ingredients on the Daily Pharmacy Drug Claim Ledger form (DMAS-173), Point-of-Service (POS) on-line billing, or other approved electronic billing method.

Multiple therapies of different therapies under pharmacy will be reimbursed at 100% for each therapy and may be billed on the HCFA-1500 (12-90) claim form. Bill for the active ingredient on the Daily Pharmacy Drug Claim Ledger form (DMAS-173), Point-of-Service (POS) on-line billing, or other approved electronic billing method.

Pharmacy

The service day rate for covered I.V. services is explained below. The rate for TPN therapy includes the usual components of this therapy. However, the service day rate does not include the fluids for hydration therapy or the active ingredient in chemotherapy, pain management, or drug therapies. Bill for these components separately as pharmacy claims. In this manner, the active ingredient is identifiable in the Drug Utilization Review (DUR) program, the Disease State Management (DSM), and the Health Care Financing Administration (HCFA) rebate program operated by the agency.

Hydration Therapy

Definition: Hydration therapy is the intravenous administration of fluids, electrolytes, and/or other additives.

The pharmacy service day rate includes, but is not limited to:

- Drug component: Electrolytes and flushes (heparin and saline); and

- Cassettes/bags/mini-bags, mixing, and compounding.

Use HCPCS code Z7779. Bill on the HCFA-1500 (12-90) claim form.

The hydration solution is billed on the Daily Pharmacy Drug Claim Ledger (DMAS-173), Point-of-Service (POS) on-line billing, or approved electronic billing method.

Pain Management

Definition: Pain management is the intravenous administration of narcotics or other drugs to relieve pain.

The pharmacy service day rate includes, but is not limited to:

- Drug component: Diluent, electrolytes, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

Use HCPCS code Z7781. Bill on the HCFA-1500 (12-90) billing form.

Chemotherapy

Definition: Chemotherapy is the administration of chemical agents designed to have a specific effect upon disease causing cells or organisms.

The pharmacy service day rate includes, but is not limited to:

- Drug components: Diluent, electrolytes, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

Use HCPCS code Z7780. Bill on the HCFA-1500 (12-90) claim form.

Special Notes

- Hydration solutions may be billed separately (see “Hydration Therapy”).

Drug Therapy

Definition: Drug therapy is the intravenous administration of antibiotics or other drugs.

The pharmacy service day rate includes, but is not limited to:

- Drug components: Diluent, electrolytes, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

Use HCPCS code Z7782. Bill on the HCFA-1500 (12-90) claim form.

TPN

Definition: TPN is the administration of nutritional substance by intravenous infusion to nourish recipients who are malnourished or may develop malnutrition and who are not candidates for enteral support. TPN must be the sole source of nutrition.

The pharmacy service day rate includes, but is not limited to, the:

- Drug components: Diluent, electrolytes, **nutritional** additives, lipids, and flushes (heparin and saline); and
- Cassettes/bags/mini-bags, mixing, and compounding.

Use HCPCS code Z7783. Bill on the HCFA-1500 (12-90) claim form.

Special Notes

- The pharmacy service allowance includes solutions, routine additives (such as KCL, MVI), and lipids. (Insulin is an example of a medication that may be billed separately with TPN therapy.)

## COVERAGE OF WEIGHT LOSS DRUGS

Effective for dates of service on and after July 1, 1997, anorexiant drugs may be covered for recipients who meet specific disability criteria for obesity as established by the Social Security Administration (SSA) and in effect on or before April 7, 1999, and whose condition is certified as life-threatening. Effective for dates of service on and after September 1, 1999, all FDA-approved weight loss drugs may be covered for recipients who meet the same criteria as for anorexiant drugs. Such coverage shall be provided only when prior authorization has been granted by the Director of Medical Support or his designee, based on a certificate of medical need and the supporting documentation.

Providers should consider the following factors in determining the need for the use of anorexiant drugs:

- Conformity of the patient's condition to the SSA definition of *obesity* as a disability as found in *Disability Evaluation Under Social Security* (SSA Publication 64-039), Part III, § 9.09, which requires a weight in excess of 100 percent of the SSA defined desired level and a concurrent condition defined in the same section of SSA definitions relating to impairment by virtue of endocrine systems and obesity;

- Presence of a certified life-threatening condition, documented by the treating physician; Compliance with General Regulation 18 VAC 85-20-90, *Pharmacotherapy for weight loss* as set forth by the Virginia Board of Medicine, as delineated in its *Board Briefs*, Newsletter #52 (Spring 1997);

- The manufacturer's directions for the specific drug's therapy; and

- Assessment of the risk-benefit ratio related to the patient's commitment to compliance in treatment.

Documentation presented for consideration should include, but is not limited to

1. Age;
2. Height;
3. Weight;
4. Psychiatric or psychosocial evaluation;
5. Documented medical record evidence of functional disability;
6. Documented medical evidence of previous conservative medical management;
7. Documentation that other causes of obesity have been ruled out (for example, hypothyroidism);
8. Documentation of the extent of concurrent medical problems; and
9. Documentation by the attending physician certifying the determination that the patient's life is at risk due to obesity.

See "Exhibits" at the end of this chapter for a copy of the definition. Additional copies may be obtained, upon request, through Medical Support Services by calling (804) 786-8056 or sending a FAX to (804) 786-0414.

Requests for prior authorization must contain the patient's full name and 12-digit Medicaid identification number. The prescriber must also provide the name and complete address of the pharmacy which will be providing service. Send these requests to the attention of:

Director of Medical Support Services
Department of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, Virginia 23219

Pharmacists providing drugs for weight loss must submit all claims on the DMAS paper pharmacy claim form. A copy of the prior authorization approval notification must be attached to the claim. All claims for weight loss products will pend for manual review and price application. Patients who do not meet the requirements included in the PA process will be denied this service.

Effective for dates of service on and after April 1, 2000, the product orlistat, used for weight loss may also be prescribed for hypercholesterolemia. All claims for this product must be submitted on the DMAS paper claim form (DMAS 173). To identify orlistat claims being

submitted for this diagnosis, the pharmacist must enter the term "using for high cholesterol" in the comment block at the bottom of the claim form. Absent documentation of prior authorization or this notation, claims will be denied.

## PROCEDURES FOR DOCUMENTATION RELATED TO AMPHETAMINES USED FOR ATTENTION DEFICIT DISORDERS AND NARCOLEPSY, GROWTH HORMONE, AND TOTAL PARENTERAL NUTRITION SERVICES

Providers do not need to submit documentation of medical necessity to the Director of Medical Support Services at DMAS for: (1) amphetamines used for the treatment of attention deficit disorders or narcolepsy, (2) growth hormone, and (3) TPN services provided by pharmacies. However, prescribers must document the prescription order and the medical necessity of the services in the patient's medical record.

Prescribers must document the prescription order in the patient's medical record and verify the medical necessity by providing a description of the related clinical symptoms and diagnosis in the record. These documentation procedures should expedite the provision of services to Medicaid recipients. DMAS will use its post-payment utilization review to verify compliance with these requirements.

Pharmacists providing service related to amphetamines used for attention deficit disorders, narcolepsy, or growth hormone may submit these claims on-line through the Point-of-Service (POS) system, on paper claims (DMAS-173), or by other electronic billing media approved by DMAS. No attachment is required.

Anorexiants used to treat obesity require prior authorization in compliance with the Virginia *State Plan for Medical Assistance*. The *State Plan* also excludes payment for products used for weight gain. DMAS will monitor compliance with these requirements through the post-payment review process.

## VALID PRESCRIBER IDENTIFICATION NUMBERS REQUIRED

To comply with current Medicaid requirements, prescription orders for Medicaid recipients must bear the prescriber's Medicaid provider number. Effective for service dates on and after November 1, 2000, claims not bearing a valid prescriber Medicaid provider identification number will be denied.

Claims for prescription services submitted by pharmacies provide the basis of several Medicaid programs, including Drug Utilization Review, Disease State Management, Client Medical Management, and Provider Review. Inaccurate or incomplete data related to prescriber identification may negatively impact the success of these programs. Pharmacists are requested to ensure that all required information is submitted on the appropriate claim medium.

HMO providers must affix the appropriate Medicaid provider number to all prescription orders for Medicaid recipients.

Pharmacists are referred to page 6 of Chapter V to be reminded of the need to enter a valid prescriber ID number on all pharmacy claims. Based on this requirement, an on-line alert will prompt pharmacists to use a correct Medicaid prescriber identification number on all POS transactions. The message will read: "Invalid Prescriber ID – Enter Correct ID."

To assist pharmacists with using valid prescriber IDs, DMAS periodically provides a disk containing current Medicaid prescriber identification numbers to all Medicaid pharmacies requesting it. In certain unusual cases where no valid number is available, defined prescriber default numbers may be used. The number chosen as a default must accurately reflect the reason for its use. The use of the former default prescriber identification number (9900021) should be discontinued immediately. Acceptable default numbers have been defined for the following situations:

- When a Virginia prescriber is not listed (such as a new physician in practice), but is known to accept Medicaid patients, use the number **9998888**. This represents a *Virginia Medicaid Provider, Number Not on File*. The pharmacist should attempt to contact the prescriber directly to obtain the Medicaid provider number and use this default number only if the attempt is unsuccessful.

- When the prescriber does not appear on the ID listing and is known to be a non-participant in the Virginia Medicaid Program, use the number **9994441**. This represents a *Virginia Provider, Non-Medicaid Participant*.

- When the prescriber is a resident in a teaching hospital, acting in the course of that hospital's training program, the pharmacist may use the number **9996664**. This represents a *Virginia Provider, Resident in Teaching Facility*.

- When the prescriber is licensed in a state other than Virginia and is not enrolled as a Virginia Medicaid provider, the pharmacist may use the number **9992227**. This represents an *Out-of-State Provider, Not Virginia Medicaid Enrolled*.

For services provided on and after November 1, 2000, a valid prescriber identification number is mandated. The POS system will produce a pharmacist-overrideable denial. In addition, the Automated Response System (ARS) has been updated to allow queries for the correct number. Using the assigned pharmacy provider number for access, pharmacy providers may query the system.

In addition, the Automated Response System (ARS) will be updated shortly prior to the implementation of the denial process. Using the assigned pharmacy provider number for access, pharmacy providers will be able to query the system for the correct provider Medicaid identification number. At such time as this service becomes available, instructions for its use will be included in the ARS menu.

## PHARMACY PROVIDERS SUBMITTING CLAIMS ON PAPER, DISKETTE, OR TAPE

Pharmacy providers submitting claims on paper, diskette, or tape are requested to use only valid prescriber ID numbers or the acceptable defaults as listed above. Immediately discontinue the use of the current default, 9900021, as it will cease to function on November 1, 2000. Use only valid prescriber ID numbers or the default numbers listed above. The system will continue to process all claims prior to November 1, 2000, and an informational message, "Invalid Prescriber ID," will appear on the remittance advice. Effective for dates of service on or after November 1, 2000, any claim without a valid prescriber number will be denied and returned to the pharmacy for the invalid prescriber number to be corrected and resubmitted.

## PAYMENT FOR SERVICES

General Information

Medicaid participation is limited to providers who accept, as payment in full, the amounts paid by DMAS plus any deductible, copayment, or coinsurance required by the State Plan to be paid by the individual. While payments by DMAS may be less than the provider's usual and customary charge, recipients may not be charged for the difference. Recipients are only responsible for the copayment.

Payments for services will not exceed the amounts indicated for payment in accordance with the policy and methods described in the *State Plan for Medical Assistance Services* and described in 42 CFR § 447.331.

NOTE: For calculation of the billable units when dispensing multiple units of products with fractional weight or volume, the rounding up process must be done after the weight/volume of each unit is multiplied by the number of containers. Therefore, the correct way for calculating the billable quantity of 15 ampuls containing 2.5 ml each would be to multiply the volume/ampul by the number of ampuls (2.5 x 15 = 37.5ml). This total then would be rounded up to 38 ml. It would be incorrect to round the 2.5 to 3 ml and then calculate (3 x 15 = 45). To bill this amount would inflate the payment and could result in charges of Medicaid fraud.

All NDC numbers used for billing must be accurate as to manufacturer, product code, and package size. For instance, do not bill the NDC of a 100-unit package if the product was one repacked from a bottle of 1000. Do not change products being dispensed without correcting the NDC billed. Use of the correct NDC may be audited. Payment adjustments or charges of billing fraud may occur if it is shown that excessive billings were presented as a result of incorrect NDC numbers being submitted.

Payment Methodology

Payments for pharmacy products shall be the lowest of items (1) through (5):

(1) The upper limit established by the Health Care Financing Administration (HCFA) for multiple source drugs, except if "Brand Necessary" is noted on the prescription by the prescriber;

(2) The Virginia Maximum Allowable Cost (VMAC) established by the agency for multiple source drugs. Effective July 1, 2002, the definition of the Virginia Maximum Allowable Cost (VMAC) shall be based on the availability in Virginia of generic drugs which:

(a) are included in the Centers for Medicare and Medicaid Services (CMS) state drug rebate program;
(b) have been approved by the Federal Food and Drug Administration; and
(c) are included in the most current "Approved Products with Therapeutic Equivalence Evaluations" as generically equivalent.

(3) The estimated acquisition cost (EAC) established by DMAS for legend drugs. Effective July 1, 2002, EAC is defined as Average Wholesale Price (AWP) less 10.25% (AWP - 10.25%);

(4) Covered non-legend drugs and legend oral contraceptives are reimbursed using the same payment methodology as legend drugs;

(5) The provider's usual and customary charge to the public, as identified by the claim.

Payments for drugs include the allowed drug cost plus only one dispensing fee per month per patient for each specific drug entity. This reimbursement formula applies to all prescriptions dispensed to non-institutionalized recipients (effective July 1989), as well as to services for nursing facilities (effective July 1982). Copayments will be deducted where applicable.

Federal Reimbursement Limits

Under the authority of § 1902(a)(3)(A) of the Social Security Act and 42 CFR § 447.332, the Health Care Financing Administration (HCFA) establishes a specific upper limit for a multiple source drug if the following requirements are met:

- All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the current edition of the publication Approved Drug Products With Therapeutic Equivalence Evaluations (including supplements or in successor publications), and

- At least three suppliers list the drug, which has been classified by the FDA as category "A" in its publications, Approved Drug Products With Therapeutic Equivalence Evaluations (including supplements or in successor publications) in the current editions (or updates) of published compendia of cost information for drugs available for sale nationally (e.g., *Red Book*, *Blue Book*, *Medi-Span*).

Virginia Maximum Allowable Costs (VMAC)

DMAS may establish maximum allowable costs for specific multiple source drugs. Effective July 1, 2002, the definition of the Virginia Maximum Allowable Cost (VMAC) shall identify products eligible for such pricing based on the availability in Virginia of generic drugs which:

(1) are included in the Centers for Medicare and Medicaid Services (CMS) state drug rebate program;

(2) have been approved by the Federal Food and Drug Administration; and

(3) are included in the most current "Approved Products with Therapeutic Equivalence Evaluations" as generically equivalent.

Reimbursements are based on the lowest of the:

- HCFA upper limit;
- VMAC determined at the 75th percentile cost level or at the 60th percentile cost level for unit-dose dispensed drugs;
- Estimated Acquisition Cost (EAC) - Effective July 1, 2002, EAC is defined as AWP – 10.25%; or
- The pharmacy's usual and customary charge.

If a physician prefers that a more expensive brand name drug be dispensed, it must be noted "Brand Necessary" in the physician's handwriting on the prescription. This certification must be on file in the pharmacy and available for review by Program auditors. Signing the prescription on the signature line -- "Dispense as Written" -- is not sufficient for reimbursement greater than the maximum allowable cost (VMAC or HCFA). This requirement also applies to telephone orders.

Effective July 1, 2002, the specialty therapeutic drug, anti-hemophilia factor, shall be reimbursed according to the best pricing established by the Department after review of market factors and appropriate volume purchasing discounting. After protocols for participation are established by DMAS, the cost of this product shall only be reimubursed to providers who are in compliance with requirements of such protocols.

Nursing Facility Services

Payments for pharmacy services provided to recipients residing in nursing facilities are described below:

- Payments are based on the lowest of: the allowed amounts or the usual and customary charge as described above.

- Legend drugs - The allowed drug cost plus only one dispensing fee per month per patient for each specific drug. If refilled within the same calendar month, only the allowed drug cost is paid. This reimbursement formula applies to unit-dose and non-unit-dose dispensing.

- Non-legend drugs - Are paid in the same manner.

- Unit-dose - Reimbursements are also based on:

    - Certification - The pharmacy must apply for and be certified by DMAS as a provider of a 24-hour supply of tablets, capsules, and oral liquids in unit-dose packaging to qualify for unit-dose reimbursements.

    - Unit-dose packaging fee - An allowance of $0.0157 per tablet, per capsule, or per 10 ml (average dose) oral liquid for non-commercial unit-dose packaging. Each dose must be labeled with the drug name and strength, and comply with all requirements for repackaging as stated by the Board of Pharmacy.

    - Unit-dose dispensing fee - An allowance of add-on payment of a $0.01 per oral tablet or oral capsule. The add-on is also applicable to each 10 ml of oral liquid dispensed. (Effective October 1, 1990)

    - VMAC drugs - Reimbursements are based on the estimated acquisition cost not to exceed the VMAC limit for unit dose as determined by DMAS.

    - HCFA limits apply for unit-dose dispensing.

    - The metric quantity reported on the claim is expected to reflect the quantity of the drug which has been administered to the patient during the billing period.

Dispensing Fee: $4.25

**Note:** Pharmacies not certified as unit-dose providers, as well as to pharmacies that are certified as unit-dose providers, may dispense in unit-dose packaging; however, no additional fees will be added to the product cost unless the dispensing is in accordance with the DMAS definition of the term “unit-dose system”

Copayment
[Effective Date: July 1, 1992]

The following recipients are always exempt from copays:

- Children Under 21 Years Old - Identified by a Special Indicator Code of "A" on the Medicaid card

- Individuals Receiving Long-Term Care Services or Hospice Care - Identified by a Special Indicator code "B" on the Medicaid card

The following services are never subject to copay:

- Services delivered in the emergency room;
- Emergency services delivered in other settings;
- Pregnancy-related services; and
- Family planning services (including family planning drugs).

All other recipients have a Special Indicator code of "C" on their cards and are responsible for a copayment for each prescription.

Effective for dates of service on or after September 1, 2002, co-payment amounts shall be as follows:

One dollar ($1.00) co-pay for generic drug products; and
Two dollars ($2.00) co-pay for single source or “brand necessary” products.

NOTE: Prescribing physicians should indicate "PREGNANCY" on the prescription form for prescriptions related to the pregnancy for pregnant women.

Recipients have been notified that inability to pay the copayment at a particular time does not relieve them of that responsibility.

Eligible Recipients and Covered Vaccines

For Medicaid-eligible recipients, routine immunizations are covered only under Virginia Medicaid’s Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program, which covers individuals up to the age of 21. However, the federal Vaccines for Children Program (VFC) provides free vaccines for children up through the age of 18. Therefore, for children ages 19 and 20, reimbursement for vaccines will be made to any eligible provider as defined in the amended § 54-3408 of the Code of Virginia. Immunizations to all other individuals are limited except for instances when:

- The immunization is necessary for the direct treatment of an injury; or
- The immunization is a pneumococcal or influenza vaccination that is reasonable and necessary for the prevention of illness.

Any eligible Medicaid provider will be reimbursed for the cost of pneumococcal or influenza vaccines given as part of a plan of treatment which has as its objective preventing the occurrence of more serious illness in an individual “at risk.” This allows for the administration of influenza and/or pneumococcal vaccinations when these vaccinations are indicated as medically necessary. Pharmacies must maintain in their offices documentation which indicates the valid medical reason(s) justifying the administration of the influenza

and pneumonia vaccines. (Medicaid does not reimburse an administration fee to pharmacists for providing vaccines. Only the acquisition cost will be paid. Virginia's Title XXI CHIP Program, known as the Family Access to Medical Insurance Security Program (FAMIS), does cover the administrative fee of $11.00 for vaccines not provided through the VFC program).

## REIMBURSEMENT FOR VACCINES:

Legislation effective on July 1, 1997, provides for reimbursing pharmacies for vaccines for adults. The legislation amended § 54.1-3408 of the Code of Virginia relating to professional use of drugs by practitioners. Among the amendments, was the following (amended language in italics):

A "*prescriber* may authorize, *pursuant to a protocol approved by the Board of Nursing,* the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, (i) *by licensed pharmacists,* (ii) by registered nurses or (iii) licensed practical nurses under the immediate and direct supervision of a registered nurse..."

Effective for dates of service on and after July 1, 1997, these services, when provided by pharmacists operating under such an approved protocol, are covered when billed to Medicaid for eligible recipients. Do not bill Medicaid for Medicaid recipients also covered by Medicare. Submit claims to Medicare in these instances, as Medicaid is the payer of last resort.

Claims for immunizations provided to adults must be billed on the HCFA-1500 (12-90) claim form (see "Instructions for Billing for Vaccines on the HCFA-1500 (12-90) Claim Form" in Chapter V). These services cannot be billed on-line via the Point-of-Service (POS) computer system. Pharmacists must bill Medicaid directly under their own Medicaid provider numbers for these immunizations even if they choose to subcontract with a home health agency to provide the immunizations.

## CLIENT MEDICAL MANAGEMENT PROGRAM

As described in Chapters III and VI of this manual, DMAS may designate certain recipients to be restricted to specific physicians and pharmacies. When this occurs, it is noted on the Medicaid recipient's ID card. A Medicaid-enrolled pharmacy that is not the designated provider may provide and be paid for services to these recipients only under the following circumstances:

- In a medical emergency where a delay in treatment may cause death or result in a lasting injury or harm to the recipient, and
- When the designated pharmacy does not stock or is unable to obtain the drug.

Appropriate billing instructions for these situations are covered in Chapter V of this manual.

For more specific information on the Client Medical Management Program, refer to Chapter VI.

## MEDICARE CATASTROPHIC COVERAGE ACT OF 1988

[Effective Date: January 1989]

The Medicare Catastrophic Coverage Act of 1988 and other legislation require State Medicaid Programs to expand the coverage of services to certain low income Medicare beneficiaries, known as Qualified Medicare Beneficiaries (QMBs).

QMB Coverage Only

Recipients in this group are eligible only for Medicaid coverage of Medicare premiums and of deductible and coinsurance up to the Medicaid payment limit less the recipient's copayment on allowed charges for all Medicare-covered services. They will receive Medicaid cards with the message "QUALIFIED MEDICARE BENEFICIARY--QMB--MEDICAID PAYMENT LIMITED TO MEDICARE COINSURANCE AND DEDUCTIBLE." Medicaid payment of the Medicare coinsurance is limited to the Medicaid fee when combined with the Medicare payment.

QMB Extended Coverage

Recipients in this group will be eligible for Medicaid coverage of Medicare premiums and of deductible and coinsurance up to the Medicaid payment limit on allowed charges for all Medicare-covered services plus coverage of all other Medicaid-covered services listed in Chapter I of this manual. This group will receive Medicaid cards with the message "QUALIFIED MEDICARE BENEFICIARY--QMB EXTENDED." These recipients are responsible for copay for pharmacy services, health department clinic visits, and vision services.

All Others

Recipients without either of these messages on their Medicaid cards will be eligible for those covered services listed in Chapter I of this manual.

## SUBMISSION OF CLAIMS FOR NONRESIDENT ALIENS

Chapters I and III contain information on the coverage and eligibility requirements for nonresident aliens. To submit a claim for covered emergency services for a nonresident alien :

- Complete the appropriate Medicaid billing form (and any other required forms) in the usual manner.
- Attach a copy of the completed Emergency Medical Certification Form to the invoice. Other relevant documentation to justify the approval has already been

submitted and reviewed and therefore does not need to be duplicated with this claim.

- Submit the claim by mailing the claim directly to the appropriate post office box.

NOTE: The same procedures apply for adjusted or voided claims for these patients.

All claims for nonresident aliens will pend for certification to verify that they were related to the emergency situation which has been approved. All claims not related to the emergency treatment will be denied. The documentation for a denied claim will be kept by Medicaid for 180 days from the date of receipt to allow for the appeal process for those services which are not approved.

## POINT-OF-SERVICE (POS) PRESCRIPTION DRUG PROGRAM

The Point-of-Service (POS) Prescription Program is available to retail pharmacies only. Unit dose prescriptions must continue to be filed either on paper or approved electronic media (magnetic tape, diskette, etc.). In addition to the POS system, Virginia Medicaid provides a Prospective Drug Utilization Review (ProDUR) Program. However, ProDUR is only available to pharmacies submitting claims through on-line Point-of-Service. Retail pharmacies may continue to submit claims by magnetic tape, diskette, or paper. Medicaid does not require that retail claims be submitted through the on-line POS system.

Point-of-Service is a computerized claims submission process for retail pharmacies. It provides the pharmacy another claims submission option besides electronic media and paper with the added advantage of an on-line, real-time environment which provides immediate adjudication of claims.

Pharmacies electing to submit claims through Point-of-Service must make necessary arrangements through their software vendors with regard to equipment, input lines, and testing. First Health Services Corporation will notify the provider when on-line access to Point-of-Service is available to the provider.

### Requirements for Submission of Claims Through POS

Virginia Medicaid requires that a pharmacy submitting POS claims use Version 3.2, format "C," a standard format developed by the National Council for Prescription Drug Programs (NCPDP). Software capable of producing claims in this format may be obtained from a number of vendors. First Health Services Corporation, DMAS' fiscal agent, must certify the software before claims can be accepted. Arrangements for a switching company can be made directly or through the provider's software vendor. The switch or network serves as a communication link between the pharmacy and First Health Services Corporation.

### How to Enroll as a POS Pharmacy

The following steps must be completed prior to submitting Point-of-Service claims: a Pharmacy Point-of-Service Authorization form must be completed by the provider; testing

must be completed (see the "Exhibits" section at the end of this chapter for a sample form); and an authorized approval letter must be obtained from DMAS. Chain pharmacies must return their completed POS Authorization form to their billing headquarters. All other pharmacies must return their completed POS Authorization forms directly to:

POS Coordinator
First Health Services Corporation
P.O. Box 3900
Glen Allen, Virginia 23058

Submission of POS claims may not take place until an authorized approval letter has been sent to the pharmacy by DMAS.

How Claims are Transmitted Through POS

Point-of-Service claims are transmitted through a telephone line to a telecommunication network. Once the network receives the claim data, it is forwarded to Virginia Medicaid's fiscal agent for processing. System availability historically has exceeded 99 per cent. The average pharmacy transaction from the time the pharmacist presses the ENTER key until a return response is generally less than 30 seconds.

Claims submitted through on-line POS go through various system edits similar to those used for magnetic tape, diskettes, and paper claims. The system edits include provider and recipient eligibility checks, program-specific claims adjudication edits, and Prospective Drug Utilization Review edits. Some edits will require a response or override. Once the processing is finished, a paid or denied response is returned. No claims will pend when submitted through on-line POS.

Adjudication of Claims

Claims submitted through on-line POS will be either paid or denied. Since POS claims are processed on-line in a real-time environment, the provider will no longer experience pended claims. Therefore, there may be situations in which claims that previously pended for manual review will now pay or deny on-line. For reconsideration of the following denial reasons, submit a paper claim with documentation when necessary:

- 70 NDC not on file (no documentation required)
- 75 Prior authorization required (documentation required)
- 76 Dispensing unit outside program minimum-maximum allowance (documentation required)
- 78 Charges exceed maximum allowance (documentation required)
- 81 Claim filed after 1-year limit not justified (documentation required to justify late filing)
- 83 Duplicate of history file record (documentation required)

- 83 Duplicate RX number/different drug code (documentation required)
- 83 Two providers same service/date of service (documentation required)
- M5 Not processable by POS - submit paper claim

Also, because on-line POS claims are not pended for manual review, there are certain claims which cannot be processed through Point-of-Service. The following claims must be submitted on paper with documentation. If submitted through on-line POS, these claims will deny. The types of claims are:

- Compounds
- Filing date greater than 1 year from date of service
- NDC not activated (deny reason 423, no documentation required)
- Charges greater than $9,999.99
- Prior authorized drugs
- Orlistat (When used for treatment of obesity, PA documentation must be attached to paper claim. If being used for treatment of high cholesterol, a notation to that effect must be made in the explanation section of the paper claim.)
- Claims receiving both "Early Refill" and "Therapeutic Dupe" alerts

With respect to the effects of the Prospective Drug Utilization Review (ProDUR) Program on the adjudication of claims, refer to the information in the ProDUR section below.

## THIRD PARTY LIABILITY (TPL) PROCEDURES FOR POS PHARMACY CLAIMS

In order to conserve Medicaid dollars, and as payer of last resort on pharmacy claims, DMAS is beginning a process of Coordination of Benefits (COB) for Third Party Liability (TPL) collections at the point of service. For pharmacy claims having a service date on or after July 1, 2002, DMAS will send an on-line claim denial message to pharmacy providers submitting claims for which the patient has other insurance coverage. The messages used in this project are shown in the table below.

| *VA Code* | *Virginia Denial Message Text* | *NCPDP Code* | *NCPDP Reject Message Text* |
|---|---|---|---|
| 313 | Bill Any Other Available Insurance | 41 | Submit Bill To Other Processor Or Primary Payor |
| 387 | Primary Carrier Payment Needs Explanation | 13 | Missing/Invalid Other Coverage Code |

DMAS requests that providers receiving either of these messages verify whether the patient has additional coverage. If the patient acknowledges such coverage, the pharmacist should submit the claim first to that third party. Once the other insurer adjudicates the claim, the claim may be resubmitted to DMAS using appropriate messages in NCPDP data element fields, "OTHER COVERAGE CODE" and "OTHER PAYER AMOUNT". These fields are included in existing payer specifications. In order to submit an over ride to the denial, the pharmacist must use the appropriate response in each field as shown below. In the case where a patient denies having additional coverage, the responses to be used in these fields are also noted below.

The pharmacy TPL editing is based on the NCPDP "Other Coverage Code" standard values (Version 3.2). These values and their definitions are as follows:

0 - Not specified
1 - No other coverage identified
2 - Other coverage exists - payment collected
3 - Other coverage exists - this claim not covered
4 - Other coverage exists - payment not collected

Below is a grid reflecting the combination of Other Coverage Code, presence or absence of a third party payment amount and whether or not the recipient's record indicates third party pharmacy coverage with the proposed corresponding claim disposition.

| *Other Coverage Code* | *TPL Amt* | *TPL indicated on Recipient's record* | *Initial Claim Disposition* | *Override process* |
|---|---|---|---|---|
| 0 = Not Specified | 0 | Yes | Deny, Bill Other Carrier VA code 313/NCPDP code 41 | Provider can resubmit with an Other Coverage Code of 3 or 4 as appropriate. |
| 0 = Not Specified | 0 | No | Pay | |
| 0 = Not Specified | >0 | Yes or No | Deny, *TPL Indicators Conflict* VA code 387/NCPDP code 13 | Provider can resubmit with corrected Other Coverage Code or zeros in TPL Amount. |
| 1 = No Other Coverage Identified | 0 | Yes | Deny, Bill Other Carrier VA code 313/NCPDP code 41 | Provider can resubmit with an Other Coverage Code of 3 or 4 as appropriate. |
| 1 = No Other Coverage Identified | 0 | No | Pay | |
| 1 = No Other Coverage Identified | >0 | Yes or No | Deny, *TPL Indicators Conflict* VA code 387/NCPDP code 13 | Provider can resubmit with corrected Other Coverage Code or zeros in TPL Amount. |

| *Other Coverage Code* | *TPL Amt* | *TPL indicated on Recipient's record* | *Initial Claim Disposition* | *Override process* |
|---|---|---|---|---|
| 2 = Other coverage exists, payment collected | 0 | Yes or No | Deny, *TPL Indicators Conflict* VA code 387/NCPDP code 13 | Provider can resubmit with corrected Other Coverage Code or TPL Amount. |
| 2 = Other coverage exists, payment collected | >0 | Yes or No | Pay | Payment = Calculated Amount minus Other Payer Amount |
| 3 = Other coverage exists, this claim not covered | 0 | Yes or No | Pay | This code should be used when the drug is not covered by the other carrier |
| 3 = Other coverage exists, this claim not covered | >0 | Yes or No | Deny, *TPL Indicators Conflict* VA code 387/NCPDP code 13 | Provider can resubmit with corrected Other Coverage Code if wrong code entered or enter zeros in TPL Amount if Other Coverage Code was entered correctly. |
| 4 = Other coverage exists, payment not collected | >0 | Yes or No | Deny, *TPL Indicators Conflict* VA code 387/NCPDP code 13 | Provider can resubmit with corrected Other Coverage Code or zeros in TPL Amount. |
| 4 = Other coverage exists, payment not collected | 0 | Yes or No | Pay | This code should be used when the drug is covered by the other carrier but the pharmacy has not been able to collect from the other resource. |

If a patient denies having other coverage, the pharmacist should use the appropriate override codes and fill the prescription as if it were a "pay and chase" claim. Until future notice, such claims will be handled under the "pay and chase" waiver. Pharmacists are requested to make every effort to capture TPL payments where possible in order to maximize the potential cost savings to the Medicaid program.

Virginia Medicaid, always the payer of last resort, will only pay claims to the maximum of the Virginia Medicaid Allowed Amount. The coordinated benefit payment of the TPL amount and any additional Medicaid payment will be equivalent to the appropriate payment allowed under DMAS payment rules. Therefore, the total payment may not appear to correspond to the submitted claim amount. The final adjudication under Medicaid will show the appropriate co-pay to be collected from the patient.

## PROSPECTIVE DRUG UTILIZATION REVIEW (PRODUR) SYSTEM

The ProDUR system functions in conjunction with the POS Program. As a pharmacy claim is being electronically edited for eligibility and claims adjudication, the claim may also be edited against selected drug use criteria. Since this edit (review) occurs before the prescription is filled, it is a prospective system. All ProDUR criteria have been reviewed, revised, and approved by the Virginia DUR Board, a group of pharmacists and physicians who oversee the DMAS DUR activities. If an exception to one or more ProDUR criteria is identified, a message will be transmitted on line to the pharmacist. The pharmacist has the opportunity to use the message as the focus of patient counseling or prescriber communication. Among NCPDP standardized messages which the pharmacist may receive are messages identifying drug interactions, age contraindication, drug-disease contraindication, pregnancy contraindication, excessive dose with/without an age qualifier, insufficient dose with/without an age qualifier, early refill, under utilization (late refill) and therapeutic duplication.

Claims may be denied due to the exceptions to one or more ProDUR criteria.

ProDUR implementation does not impact the claims adjudication edits, such as eligibility verification.

For Point-of-Service transmission problems or POS set-up information, contact the First Health PRN Help desk at 1-800-884-3238.

## DENIAL FOR PAYMENT OF ANTIULCER DRUGS USED BEYOND ACUTE TREATMENT LIMITS

The POS system will edit all claims in the antiulcer category for correct dose and duration. The criteria used will be those defined by the DMAS Drug Utilization Review (DUR) Board. The criteria contain information about correct dose for acute treatment and for maintenance therapy, as well as the appropriate duration of treatment in the high-dose categories. Dose calculations will be based on the days' supply entered by the dispenser. If the use of a product exceeds the maximum dose or duration limit, a message will appear on the user's screen indicating that payment is denied. If there is a valid reason for continued high dose use, the pharmacist must enter the appropriate override code into the system to document the reason.

Pharmacist-initiated overrides may be utilized in the following circumstances by using the appropriate code.

For anti-ulcer preparations, the following message will appear in the alert/deny field, "**Maint.dose/duration exceeded-Give diag**."

Valid reasons and the associated override codes for this message are:

| REASON | PA + CODE |
|---|---|
| Initial Therapy | 5 55555555520 |

| REASON | PA + CODE |
|---|---|
| Gastroesophageal Reflux Disease (GERD) | 5 55555555521 |
| Pathological Hypersecretory Syndrome | 5 55555555522 |
| Zollinger-Ellison Syndrome | 5 55555555523 |
| Unhealed Ulcer (gastric, duodenal, peptic) | 5 55555555524 |
| History of Upper GI Bleeding | 5 55555555525 |
| Erosive Esophagitis | 5 55555555526 |

Doses in excess of the manufacturer's recommendations for dose level or duration are subject to this edit and may be denied unless the prescriber indicates in his own handwriting the exception reason on the face of the prescription. The dispensing pharmacist must verify the reason *each time* a denial message is generated from Medicaid. "Automatic" overrides are not permitted. The provider should check with his software vendor to be sure that the program does not replicate the override on subsequent submissions. Providers' use patterns will be monitored, and high utilization of the override capability may precipitate an audit of claims submissions.

Maintenance level use of antiulcer products will be screened for duration of use. Appropriate prescriber consideration must be given to continued dosing at maintenance levels beyond the manufacturer's recommendation. Prescribers are encouraged to consider diagnostic testing or treatment for *H. Pylori* in the determination of continued treatment in refractory cases.

To override the payment denial edit, the provider must enter a 5 in the prior authorization/medical certification (PA/MC) field (defined as field 416-DG in National Council for Prescription Drug Programs [NCPDP] standards). Using the additional 11-digit reason code then enters the specific reason.

The First Health Services Technical and ProDUR Help Desks are NOT available to assist providers with resolving questions related to this override function. For assistance, use the DMAS HELPLINE at the numbers listed in Chapter I of this manual.

## DENIAL OF PAYMENT FOR EARLY REFILLS AND THERAPEUTIC (CLASS) DUPLICATION IN CERTAIN DRUGS AND MECHANISM AND PROCEDURES FOR PHARMACIST-INITIATED OVERRIDE IN VALID REASON CATEGORIES

DMAS has an early refill denial edit and therapeutic (class) duplication edit as an enhancement of the Medicaid ProDUR activities requirement. These Point-of-Service (POS) edits expand ProDUR activities to include the denial of unjustified requests for early prescription refills or therapeutic (class) duplicate products. A mechanism has been provided for override of the denial in unusual situations as identified below.

"Early refill" is defined as "when a prescription refill is requested before 75% of the calculated days' supply has elapsed for the previously filled prescription." Providers must take extra care in verifying that a correct amount is shown for the "days' supply" entry for all prescriptions.

A denial edit for therapeutic duplication will occur when a product in the same therapeutic drug class as a concurrently utilized product (e.g., concurrent use of two calcium channel blockers) is billed. The following groups of drugs will be subject to therapeutic duplication alerts:

- ACE Inhibitors;
- Antidepressants;
- Anti-Ulcer;
- Benzodiazepines;
- Calcium Channel Blockers;
- Cardiac Glycosides;
- Diuretics; and
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

An early refill claim or a therapeutic duplication within certain drug classes will be denied payment. The error code and message will appear on both the computer screen and the remittance advice.

The error codes and error message associated with the denial edits are:

| State Error Code | NCPDP Error Code | Message |
|---|---|---|
| **418** | **79** | **Early Refill/ProDUR** |
| **438** | **TD** | **Therapeutic Duplication/ProDUR** |

Although the error alert code and/or message appearing on the screen may vary in individual practice settings due to the configuration chosen by the software vendor providing POS access, the denial of payment will be shown by some combination of the error codes noted above with a message explaining the code. A payment denial code will require the provider to reverse the claim except in those cases where a valid reason can be documented for the need to override the denial. Overrides of the denial must be entered into NCPDP field 416 (PA/MC Code and Number). The provider should make sure that the software vendor verifies that this field is set up and active in the system.

Pharmacy providers will be able to initiate an override in the POS system in cases where, according to specific parameters, the need for an early refill or therapeutic duplication is justified. The valid reason for override must be documented in the system (NCPDP Field 416) and in the prescription records of the pharmacy. The pharmacy copy of the reason for the override may be recorded on the back of the prescription hard copy or in a log or ledger of the provider's choice, as long as it is readily accessible for review. As with all documentation related to Medicaid claims, records of overrides must be maintained for a

period of five years and must justify the override. The utilization of the override function by providers will be monitored.

In the following unusual circumstances, the pharmacist may override the denial. Pharmacists must exercise professional judgment before proceeding with the override function.

A. Only the following reasons may be used as justification for override of early refill edits:

1. **"Temporary Exemption" -** Need determined by travel distance, transportation availability, or travel out of area;
2. **"Missing Medication" -** Waste, spilled, lost, stolen, destroyed, or damaged drug supply;
3. **"Data Entry Error (days' supply)" -** Keying error or underestimation of use pattern; and
4. **"Clinical Justification" -** Dose increase authorized by the prescriber, etc.

B. Only the following reasons may be used as justification for override of the therapeutic duplication edit:

1. **"Original Drug Discontinued. New Drug Ordered." -** Discontinued use of one drug and subsequent new prescription issued in the same therapeutic drug class (e.g., substitution of one calcium channel blocker for another); and
2. **"Physician Contacted, Deems Duplicate Therapy Necessary."** - Pharmacist's professional judgment still must be used to ensure the patient will not be at risk from such duplication.

The following codes must be used by the pharmacist to accomplish system edit overrides:

| **Reason** | **PA Code and Number** |
|---|---|
| Temporary Exemption | 511111111111 |
| Missing Medication | 522222222222 |
| Data Entry Error (days' supply) | 533333333333 |
| Clinical Justification | 544444444444 |
| Original Drug Discontinued. New Drug Ordered. | 555555555508 |
| Physician Contacted, Deems Duplicate Therapy Necessary. | 555555555509 |

In cases where both alerts are generated, the system will alternately display one, then the other repeatedly. It is not possible to negate this loop by entering an override code. In such situations, the provider must submit the claim on paper.

The First Health Services Technical and ProDUR Help Desks are NOT available to assist providers with resolving questions related to this override function. For assistance with questions relating to this program, use the DMAS HELPLINE.

## REIMBURSEMENT FOR MEDICATIONS SHOWING OBSOLETE NDC NUMBERS

DMAS will consider current, active NDC (National Drug Code) numbers for reimbursement of medication charges. Medication charges for products bearing obsolete NDC numbers will be denied. Numbers determined to be obsolete are based on notification in quarterly updates from the Health Care Financing Administration's Drug Rebate Program. The Medicaid Drug Rebate Program is based on NDC specific units billed and captures representative marketplace drug discounts based on accurate data invoiced each calendar year quarter to drug labelers. Incorrect/expired/terminated NDCs provide the basis for rebate disputes that delay drug rebate collections by the Commonwealth.

Regardless of the use of any commercial computer data updating service, each provider is personally responsible for submissions which are correct in all details. Failure to maintain a complete, current record of product NDCs may result in payment delays as providers must resubmit corrected claims denied for obsolete products. To be assured of proper, timely reimbursement, providers should check each stock package used against the billing to be submitted. It is important to be sure that billings are made based on actual stock used.

## PHARMACY COVERAGE FOR OUTPATIENTS INCLUDING PAYMENT FOR CERTAIN OVER-THE-COUNTER (OTC) PRODUCTS WHEN USED AS THERAPEUTIC ALTERNATIVES TO MORE COSTLY LEGEND DRUGS AND PAYMENT METHODOLOGY FOR OTC PRODUCTS

The Board of Medical Assistance Services (BMAS) has determined that certain categories of over-the-counter (OTC) products also may be used appropriately as less costly therapeutic alternatives to similar categories of prescription-only (legend) drugs in the outpatient setting.

This initiative allows the use of cost-saving alternatives in the prescription program. Therefore, these products should only be prescribed for outpatients *when the provider otherwise would have used a more expensive legend product*. Note that it is possible to titrate the dose of many of these agents. In this manner, health professionals may choose to adjust the dose or product to suit the individual needs of the patient.

The choice of whether or not to use these additional products is to be determined by the patient's prescribing health care provider. This expansion of OTC coverage in the outpatient population does not affect the current coverage standards for categories of drugs included for OTC coverage in the nursing facility environment.

Effective for dates of service on and after February 1, 1997, additional OTC categories of products available for selected outpatients are:

| | |
|---|---|
| Analgesics, oral | Hematinics |
| Antacids | Hydrocortisone, topical |

| | |
|---|---|
| Antidiarrheals | Laxatives, Bulk Producers, Stool Softeners |
| Antifungals, topical | Pediculocides/Scabicides |
| Antihistamines | Vitamins, Pediatric (in established deficiencies) |
| Anti-infective agents, vaginal | Vitamins, Prenatal |
| Anti-inflammatory agents, oral | Vitamins or Minerals for dialysis patients |
| Antiulcer Preparations | |

Requests for OTC products will be handled in the same manner as prescriptions. The order may be written as a prescription or transmitted to the pharmacy by any other means which complies with the regulations of the Board of Pharmacy. Documentation is handled in the same manner as prescription drug orders. If the order is not received as a written document, the information must be reduced to writing and filed sequentially, as with any legend drug order. All requirements for storage and retrieval of documents must be observed. The product must be labeled according to the prescriber's order and appropriate counseling must be offered to the patient.

Products covered under this program must be supplied by companies participating in the HCFA Medicaid rebate program. Use of the correct NDC or UPC number is required for payments.

## CLIENT APPEALS OF THE DENIAL OF SERVICES

Any denial of a service decision made by DMAS staff may be appealed to the Department of Medical Assistance Services. This decision must be appealed in writing by the client or his or her legally appointed representative. If possible, please include a copy of the denial with the appeal request. All appeals must be filed within 30 days of the date of the final decision notification. Direct appeals to:

Division Appeals
Department of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, Virginia 23219

# EXHIBITS

Department of Medical Assistance Services
Pharmacy Point of Sale Authorization

The following constitutes a service agreement between _____ (hereinafter called "Provider") and the Department of Medical Assistance Services or its fiscal agent for the Medicaid Program, First Health Services Corporation (hereinafter called "DMAS/First Health Services").

**To be completed by the provider:**

Provider Number:_____

Provider Name:_____

Address:_____
Street No. and P.O. Box

_____
City State ZIP Code

Telephone Number: (_____)_____
Area Code Contact Person

I understand that I am responsible for the information presented on claims submitted and that the information is true, accurate, and complete. I further understand that payment and satisfaction of these claims will be from federal and state funds and that false claims, statements, documents, or concealment of material facts may be prosecuted under applicable federal or state laws.

_____
Pharmacy Authorized Signature Date

**To be completed by DMAS/First Health Services:**

This authorization will begin on _____
The provider is authorized by DMAS/First Health Services to submit Point-of-Sale billings for Virginia Medicaid pharmacy claims contingent upon the policies and specifications published in the "Virginia Medicaid Pharmacy Provider Manual and Point-of-Sale publications".

_____
Pharmacy Point-of-Sale Coordinator Date
DMAS/FirstHealth Services

Return completed form to:

P.O.S. Coordinator
First Health Services Corporation
P.O. Box 3900
Glen Allen, Virginia 23058

***Disability Evaluation Under Social Security* (SSA Publication 64-039), Part III, § 9.09**

9.09 Obesity. Weight equal to or greater than the values specified in Table I for males, Table II for females (100 percent above desired level), and one of the following:

A. History of pain and limitation of motion in any weight-bearing joint or the lumbosacral spine (on physical examination) associated with findings on medically acceptable imaging techniques of arthritis in the affected joint or lumbosacral spine; or

B. Hypertension with diastolic blood pressure persistently in excess of 100 mm.Hg measured with appropriate size cuff; or

C. History of congestive heart failure manifested by past evidence of vascular congestion such as hepatomegaly, peripheral or pulmonary edema; or

D. Chronic venous insufficiency with superficial varicosities in a lower extremity with pain on weight bearing and persistent edema; or

E. Respiratory disease with total forced vital capacity equal to or less than 2.0 L. or a level of hypoxemia at rest equal to or less than the values specified in Table III-A or III-B or III-C.

| Table I — Men (Metric) | |
|---|---|
| Height without shoes (centimeters) | Weight (kilograms) |
| 152 | 112 |
| 155 | 115 |
| 157 | 117 |
| 160 | 120 |
| 163 | 123 |
| 165 | 125 |
| 168 | 129 |
| 170 | 134 |
| 173 | 137 |
| 175 | 141 |
| 178 | 145 |
| 180 | 149 |
| 183 | 153 |
| 185 | 157 |
| 188 | 162 |
| 190 | 165 |
| 193 | 170 |

| Table II — Women (Metric) | |
|---|---|
| Height without shoes (centimeters) | Weight (kilograms) |
| 142 | 95 |
| 145 | 96 |
| 147 | 99 |
| 150 | 102 |
| 152 | 105 |
| 155 | 107 |
| 157 | 110 |
| 160 | 114 |
| 163 | 117 |
| 165 | 121 |
| 168 | 125 |
| 170 | 128 |
| 173 | 132 |
| 175 | 135 |
| 178 | 139 |
| 180 | 143 |
| 183 | 146 |

| Table I — Men | |
|---|---|
| Height without shoes (inches) | Weight (pounds) |
| 60 | 246 |
| 61 | 252 |
| 62 | 258 |
| 63 | 264 |
| 64 | 270 |
| 65 | 276 |
| 66 | 284 |
| 67 | 294 |
| 68 | 302 |
| 69 | 310 |
| 70 | 318 |
| 71 | 328 |
| 72 | 336 |
| 73 | 346 |
| 74 | 356 |
| 75 | 364 |
| 76 | 374 |

| Table II — Women | |
|---|---|
| Height without shoes (inches) | Weight (pounds) |
| 56 | 208 |
| 57 | 212 |
| 58 | 218 |
| 59 | 224 |
| 60 | 230 |
| 61 | 236 |
| 62 | 242 |
| 63 | 250 |
| 64 | 258 |
| 65 | 266 |
| 66 | 274 |
| 67 | 282 |
| 68 | 290 |
| 69 | 298 |
| 70 | 306 |
| 71 | 314 |
| 72 | 322 |

| Table III — A | |
|---|---|
| Arterial PCO2 (mm. Hg) and | Arterial PCO2 Equal to or Less than (mm. Hg) |
| 30 or below | 65 |
| 31 | 64 |
| 32 | 63 |
| 33 | 62 |
| 34 | 61 |
| 35 | 60 |
| 36 | 59 |
| 37 | 58 |
| 38 | 57 |
| 39 | 56 |
| 40 or above | 55 |

| Table III — B | |
|---|---|
| Arterial PCO2 (mm. Hg) and | Arterial PCO2 Equal to or Less than (mm. Hg) |
| 30 or below | 60 |
| 31 | 59 |
| 32 | 58 |
| 33 | 57 |
| 34 | 56 |
| 35 | 55 |
| 36 | 54 |
| 37 | 53 |
| 38 | 52 |
| 39 | 51 |
| 40 or above | 50 |

| Table III — C<br>(Applicable at test sites over 6,000 feet above sea level) | |
|---|---|
| Arterial PCO2 (mm. Hg) and | Arterial PCO2 Equal to or Less than (mm. Hg) |
| 30 or below | 55 |
| 31 | 54 |
| 32 | 53 |
| 33 | 52 |
| 34 | 51 |
| 35 | 50 |
| 36 | 49 |
| 37 | 48 |
| 38 | 47 |
| 39 | 46 |
| 40 or above | 45 |